UNITED STATES DISTRICT COURT
DISTRICT OF UTAH

IN RE: BIOMET M2a MAGNUM HIP IMPLANT PRODUCTS LIABILITY JOHN FRITSCHLE, Plaintiff, vs. BIOMET, INC.; BIOMET ORTHOPEDICS, LLC; BIOMET U.S. RECONSTRUCTION, LLC; and BIOMET MANUFACTURING, LLC, Defendants.	**COMPLAINT** **JURY TRIAL DEMANDED**

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, JOHN FRITSCHLE, by and through his attorney, Nancy A. Mismash of Robert J. DeBry & Associates, hereby alleges as follows:

NATURE OF THE ACTION

1. Defendants have known that their hip replacement device (the M2a-38 Hip Replacement System, hereafter, the "Device") is prone to fail years before its expected life. They have also known that the implant's metal "ball" and "socket" bearings that make up the hip joint generate metal debris over time from wear and tear that can spread throughout the patient's surrounding bone and tissue. As a result of these defects, patients who have had the Devices implanted have endured, or will endure, unnecessary pain and suffering; debilitating lack of mobility; inflammation which can lead to damage or death of surrounding tissue and bone; and a

subsequent more difficult revision surgery to replace the faulty Devices, giving rise to still more debilitation, a prolonged recovery time, and an increased risk of complications and death from surgery. Rather than recalling the Device upon receiving notice of complaints made to the United States Food and Drug Administration ("FDA") regarding the defects discussed above, or warning physicians and patients of these risks and precautions such as metal level monitoring, Defendants continued to aggressively market the Device, claiming it was a safe and effective hip replacement system. Indeed, Defendants sought to capitalize on the problems with the competitor devices by asserting the superiority of the Device over other metal-on-metal hip implant designs sold by their competitors. The suffering and damages incurred by Plaintiff herein could easily have been prevented. Plaintiff would not have suffered from unnecessary pain and debilitation, as well as the need to undergo subsequent revision surgery, had Defendants taken the affirmative step of recalling the Device (especially when dozens of complaints were first being made to the FDA regarding the Device's failures), or had Defendants at least warned the orthopedic surgical community and the public of the dangers of the Device so that those who had the Device implanted could be medically monitored for signs of the Device malfunctioning including loosening and metal debris related injury. Plaintiff seeks redress for Plaintiff's injuries and associated damages that have been incurred as a result of those injuries.

2. This is a tag along action to the multi-district litigation over Biomet metal-on-metal hip implants which is styled *In Re: Biomet M2a Magnum Hip Implant Products Liability Litigation (MDL 2391)* pending in the United States District Court for the Northern District of Indiana, South Bend Division, Cause No. 3:12-md-2391 before United States District Court Judge Robert L. Miller, Jr.

PARTIES

3. Plaintiff JOHN FRITSCHLE is a resident and citizen of North Ogden, Weber County, State of Utah, and has been injured due to a defective medical prosthesis manufactured by Defendants.

4. At all times relevant, Defendant, BIOMET, INC. was an Indiana Corporation with its principal place of business in Warsaw, Indiana.

5. Defendant BIOMET, INC. designed, manufactured, marketed, promoted, and sold the Device that was implanted into Plaintiff's body and is the subject of this action.

6. At all times relevant, Defendant, BIOMET ORTHOPEDICS, LLC was a limited liability company organized and existing under the laws of Indiana with its principal place of business in Warsaw, Indiana. The sole member of BIOMET ORTHOPEDICS, LLC is BIOMET, INC., which is incorporated in Indiana and has its principal place of business in Warsaw, Indiana.

7. Defendant BIOMET ORTHOPEDICS, LLC designed, manufactured, marketed, promoted, and sold the Device that was implanted into Plaintiff's body and is the subject of this action.

8. At all times relevant, Defendant, BIOMET U.S. RECONSTRUCTION, LLC was a limited liability company organized and existing under the laws of Indiana with its principal place of business in Warsaw, Indiana. The sole member of BIOMET U.S. RECONSTRUCTION, LLC is BIOMET, INC., which is incorporated in Indiana and has its principal place of business in Warsaw, Indiana.

9. Defendant BIOMET U.S. RECONSTRUCTION, LLC designed, manufactured, marketed, promoted, and sold the Device that was implanted into Plaintiff's body and is the subject of this action.

10. At all times relevant, Defendant, BIOMET MANUFACTURING, LLC, f/k/a BIOMET MANUFACTURING CORP. was a limited liability company organized and existing under the laws of Indiana with its principal place of business in Warsaw, Indiana. The sole member of BIOMET MANUFACTURING, LLC is BIOMET, INC., which is incorporated in Indiana and has its principal place of business in Warsaw, Indiana.

11. Defendant BIOMET MANUFACTURING, LLC, f/k/a BIOMET MANUFACTURING CORP. designed, manufactured, marketed, promoted, and sold the Device that was implanted into Plaintiff's body and is the subject of this action.

12. Defendants, BIOMET, INC., BIOMET ORTHOPEDICS, LLC, BIOMET U.S. RECONSTRUCTION, LLC, and BIOMET MANUFACTURING, LLC are collectively referred to herein as "Biomet" or Defendants.

13. At all times relevant herein, Defendants were the agents of each other, and in doing the things alleged herein, each Defendant was acting within the course and scope of its agency and was subject to and under the supervision of each and every other Defendant herein.

14. Upon information and belief, at all times herein mentioned, the employees of all Defendants herein, their subsidiaries, affiliates, and other related entities, as well as the employees of Defendants' subsidiaries, affiliates, and other related entities, were the agents, servants and employees of Defendants, and at all relevant times, were acting within the purpose and scope of said agency and employment. Whenever reference in this Complaint is made to any act or transaction of Defendants, such allegations shall be deemed to mean that the principals,

officers, employees, agents, and/or representatives of Defendants herein committed, knew of, performed, authorized, ratified and/or directed such act or transaction on behalf of Defendants herein while actively engaged in the scope of their duties.

JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a) as the parties are citizens of different states, and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

16. Venue is proper in the United States District Court for the District of Utah pursuant to 28 U.S.C. § 1391(b)(2) and 1391(c)(2), because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred within the District of Utah, and because Defendants are entities who are subject to the personal jurisdiction of Utah courts with respect to the civil action in question.

17. Because the claims in this case arise from a faulty Biomet hip implant, the case should be consolidated with MDL 2391, *In Re: Biomet M2a Magnum Hip Implant Products Liability Litigation,* in the United States District Court, Northern District of Indiana, South Bend Division before the Hon. Robert L. Miller, Jr. Remand would be appropriate to the United States District Court for the District of Utah.

18. Plaintiff respectfully requests that, at the time of remand and transfer of this action back to the trial court for further proceedings, this case be transferred to the United States District Court for the District of Utah.

FACTUAL BACKGROUND

19. The Device was developed in order to reconstruct human hip joints that are diseased due to conditions such as osteoarthritis, rheumatoid arthritis, avascular necrosis (AVN), or fracture. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is like a ball that fits in a socket. The socket portion of the hip is called the acetabulum. The femoral head at the top of the femur bone rotates within the curved surface of the acetabulum.

20. A total hip replacement implant device typically consists of four separate components: a femoral stem, a femoral head (or ball), a liner, and an acetabular shell (socket). Usually these components are made of metal and plastic.

21. The M2A-38 Hip Replacement System (Device) has only three components: a metal femoral head, a metal taper insert, and a metal acetabulum cup. The metal femoral head can be attached to a femoral stem to complete a total hip replacement. As a result of the use of metal in the ball, taper insert, and socket components, the device is referred to by the industry as a Metal-on-Metal (MoM) Implant Device.

22. These Devices were marketed with the claim that they would last much longer than the conventional hip implant with a polyethylene or plastic liner. Indeed, Defendants marketed the Device as having many advantages over other hip replacements or hip resurfacing systems.

23. For example, Defendants advertised that "range of motion studies performed on the M2A-38 suggests an average of 154 degrees range of motion — this is more than any other

metal-on-metal system on the market", and that "the plasma spray porous coating is more than twice as resistant to cup displacement under rim load than other coatings."

24. When initially released, Defendants promoted the Device as having a metal-on-metal articulation and represented that the Device achieved "maximum range of motion, stability, and minimal wear."

25. Further, Defendants advertised that "the large 38mm bearing surface exhibits similar wear characteristics to that of the 28mm and the 32mm metal-on-metal articulations, approximately 1/350th the wear of metal-on-polyethylene."

26. Even as other MoM devices came under scrutiny for their high rates of failure over the years, Defendants continued to falsely advertise the Device as a superior and safe device, citing biased and misleading studies and data indicating that the Device was subject to reduced wear and revision.

27. Contrary to what Defendants' marketing campaigns suggest, for many years Defendants have known of the risks inherent in MoM devices, including the M2A-38 Hip Replacement System. Specifically, for several years, the FDA had been receiving complaints that the Device prematurely failed in some patients due to component loosening, dislocation, component wear, and fracture, and that these Device failures were the result of defects in the design of the Device.

28. In addition, reports were received by Defendants that the Device's "ball" and "socket"—which are both metal bearings—generate metal debris over time from normal wear, and that this debris can spread throughout the surrounding bone and tissue causing severe inflammation and damage to patients such as Plaintiff herein.

29. Defendants were aware that the British Medicines and Healthcare Products Regulatory Agency (MHRA) and the Food and Drug Administration (FDA) expressed concern about metal-on-metal hips and the impact of metal ions on patients, and, as such, Defendants (as part of industry trade groups) participated in discussions of studies of the health effects of metal-on-metal hip implants with other manufacturers during that time period.

30. Defendants' reasons for concealing defects in the Device are clear, as hip implant sales are critically important to Defendants. During the time period relevant to this action and Defendants' manufacturing and marketing of the Device, Defendants' management was trying to make Defendants look appealing to investors.

31. In fact, in 2007, Defendants were ultimately purchased by a private equity firm for $10 billion. At that critical time, Defendants were faced with defects in one of its most profitable hip implant systems, a problem that, if it were discovered or disclosed at that time, would have had significant financial ramifications for Defendants.

32. Rather than admit that these popular hip implant products had a critical defect that could cause a premature failure (which, in turn, would force patients to have to undergo another painful surgery for hip implant revision), Defendants chose to pursue corporate profits, at the expense of patient safety, and continued to promote, market, and sell the Device despite the fact that they knew the products were defective. To this day, Defendants continue to sell these defective implants to unsuspecting patients without any warning about the defective nature of the product, the safety risks to patients, or the excessive rates of failures of the Device that have been reported to Defendants.

33. In 2011, the Australian Orthopedic Association published its annual report on data collected from the Australian National Joint Registry, which tracks surgical revisions of orthopedic

devices in Australia (sadly, the United States does not have such a registry). The Australian report showed that the Device had a yearly cumulative revision rate of 7.2% after seven years, with a statistical range of 5.3% and 9.7%. This is a much higher revision rate than some other metal-on-metal hip replacement products.

34. In May of 2011, the FDA required Defendants, as well as other manufacturers, to provide data on levels of metal in the blood of patients implanted with their MoM hip implants due to rising concerns regarding the use of these implants and the safety risks that they pose to unsuspecting patients. The FDA's request followed the release of British studies from March of 2010 which showed that metal-on-metal hip implants, such as the Device, are potentially dangerous because they can generate large amounts of metallic debris that is absorbed into patients' bodies as they wear over time. Metallic debris has been shown to cause severe inflammatory responses in some patients, resulting in pain in the groin, death of tissue in the hip joint, and loss of surrounding bone. Patients who develop this severe inflammatory response often require revision surgery to replace the metal-on-metal device at a time well in advance of the life expectancy of the device, and such patients are also less likely to have successful hip implantation procedures in the future due to the severe inflammatory response and soft tissue and bone necrosis associated with metallosis and the release of metal ions from metallic debris into their bloodstream and the area surrounding the hip implant.

35. In a systematic review of clinical trials, observational studies, and registries conducted by the FDA and published in the *British Medical Journal* on November 29, 2011, it was found that MoM hip implants are no more effective than traditional polyethylene-lined implants, and that metal-on-metal hip implants are associated with an increased risk of patients requiring revision surgery. In other words, these studies show that metal-on-metal hip implants,

such as the Device manufactured and marketed by Defendants and implanted in Plaintiff's body, increase the safety risks for patients without providing any benefits over traditional hip implants.

36. Following dissemination of this data and information on this poor risk-versus-benefit profile for metal-on-metal hip implants, sales of the Device have decreased substantially.

37. As a result of the issues with the Device, recipients of the Device, including Plaintiff herein, have suffered symptoms including, but not limited to: pain; swelling; inflammation; metallosis; elevated levels of metal ions; damage to surrounding bone and tissue; and lack of mobility.

38. These symptoms are the result of (1) possible loosening of the implant, where the implant does not stay attached to the bone in the correct position; (2) fracture, where the bone around the implant may have broken; (3) dislocation, where two parts of the implant that move against each other are no longer aligned; or (4) the spread of metal debris generated from the metal femur head and metal acetabular cup rubbing and rotating against each other.

39. As a result of the foregoing symptoms, revision surgeries have been necessary to remove the faulty Devices from a number of patients. These revision surgeries present enormous risks to the patients because they are technically more difficult than the original surgery to implant the Device, the patient is more at risk of complications and death, and the recovery time is prolonged as compared to the original hip replacement surgery. Further, as a result of metallosis and bone and soft tissue destruction, patients who have been implanted with the Device and undergone a revision surgery for premature failure of the Device are less likely to have successful hip implantation surgeries in the future and face an extremely high post-operative complication rate following revision surgeries to remove a defective Device.

40. On September 17, 2007, Plaintiff underwent a righ hip total arthroplasty surgery performed by Joshua Hickman, M.D. at Lakeview Hospital in Bountiful, Utah. During that procedure, Plaintiff was implanted with the following hip implant products manufactured and marketed by Defendants herein: Biomet M2AMagnum PF cup Lot 488470, Ref: US157864; Biomet Modular Taperloc Femoral Lot 741160, Ref. 103209; Biomet M2A Magnum Modular Head Lot 724510, Ref. 157458; and Biomet M2A Magnum taper adapter Lot 506180, Ref. 139270.

41. After the surgical implantation of the Magnum Device, Plaintiff suffered symptoms including but not limited to increasingly debilitating pain, discomfort, and soreness.

42. Plaintiff additionally suffered or incurred the following personal and economic injuries as a result of the implantation with the Magnum Device:

(a) underwent an additional surgical procedure that would not have been needed if the Magnum Device had performed satisfactorily during its expected usual life;

(b) permanent harm by severe metal poisoning and metallosis from the metal debris of the Magnum Device;

(c) lost wages and future loss of earning capacity;

(d) medical expenses and will incur additional medical expenses in the future; and

(e) permanent harm because of complications normally associated with a second hip replacement.

43. On March 12, 2015, Plaintiff underwent a revison of the right hip performed by Aaron Hoffman, M.D. at Davis Hospital in Layton, Utah for a failed right total hip implant due to metalosis and elevated levels of cobalt and chromium.

44. During the March 12, 2015, right hip revision surgery, Plaintiff was implanted with the following components: Biomet acetabular cup: Ref: EP-200184, Lot. 101480; Ceramic Head: Ref: 650-1055, Lot: 027330; Taper Adapter: Ref: 650-1068, Lot 633080.

45. Revision surgeries are generally more complex than the original hip replacement surgery, often because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the original hip replacement surgery and the revision surgery has a higher rate of complications.

46. An employee and/or agent of Defendants provided the Device to Plaintiff's original implanting surgeon at the time of the original surgery to implant the Device as noted herein.

47. Beyond merely providing the Device to the surgeon, agents of Defendants were hired by Defendants to aggressively promote, distribute, and sell the Device.

48. Directors, managers, and sales representatives of Defendants received training and education from Defendants, including orthopedic and surgical training, product design rationale for the Device, education regarding proper use of the tools to implant the Device, selection of complementary components to the Device, and training on how to sell the Device to surgeons over hip replacements offered by competitors.

49. On numerous occasions, Defendants met with orthopedic surgeons, including, on information and belief, with Plaintiff's orthopedic surgeon who performed the original implantation on Plaintiff, to promote the Device.

50. At some or all of these meetings, one or more representatives of Defendants were present. During these meetings, Defendants assured the orthopedic surgeons, including (upon information and belief) Plaintiff's original implanting orthopedic surgeon, that the Device was

safe, effective, one of the best products on the market, had an excellent track record, had very low wear, would last longer than traditional hip implants, and had a low and acceptable failure rate.

51. Defendants continued to "defend" the Device even after Defendants became aware of numerous and serious complications with it.

52. Further, Defendants did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons, including Plaintiff's original implanting orthopedic surgeon.

53. Plaintiff's revision surgery has subjected Plaintiff to much greater risks of future complications than Plaintiff had before the revision surgery. For example, several studies have found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4% of patients who underwent a revision surgery suffered from a dislocation compared with 3.9% of patients who underwent an original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost four times more likely to suffer from a hip dislocation than those who have not. (Phillips CB, *et al.* Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20-26.)

54. Upon information and belief, Defendants were instrumental in educating Plaintiff's original implanting orthopedic surgeon regarding claimed advantages of the product, addressing the questions of the surgeon and providing information that the surgeon could, in

turn, share with patients such as Plaintiff herein who were contemplating hip implant surgery and making decisions regarding the type of product to be utilized for such a procedure.

55. Had Plaintiff or Plaintiff's surgeon known that the Device caused injury, posed serious safety risks, that its risks outweighed its benefits, that far safer and reliable alternatives were available, and/or the likelihood of premature device failure and the need for early revision surgery to remove the defective Device, neither Plaintiff and/or Plaintiff's original implanting surgeon would have chosen the Device for the initial hip implant surgery. Rather, Plaintiff and/or Plaintiff's original implanting surgeon would have opted for the safer and more effective traditional hip implant models.

56. As a direct and proximate result of Defendants placing the defective Device into the stream of commerce, Plaintiff has suffered, and continues to suffer, injuries and damages including, but not limited to, the following: past, present, and future physical and mental pain and suffering; past, present, and future expenses for medical, rehabilitation, and nursing care; loss of earnings and the capacity to earn a living; and loss of the quality of life. Plaintiff's spouse has suffered in the past and will continue to suffer in the future injuries and damages due to a loss of consortium as a result of injuries sustained by Plaintiff. These injuries and damages are continuing.

COUNT I
STRICT LIABILITY FOR DESIGN DEFECT

57. Plaintiff incorporates by reference, as if fully set forth herein, paragraphs 1 through 56 above, as to all Defendants and further alleges as follows.

58. At all times herein mentioned, Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed into the stream of commerce, the Device that was surgically implanted in Plaintiff herein.

59. At all times herein mentioned, the Device was in an unsafe, defective, and inherently dangerous condition for users such as Plaintiff herein in whom the Device had been surgically implanted.

60. The Device was in an unsafe, defective, and inherently dangerous condition at the time it left Defendants' possession.

61. At all times herein mentioned, the Device was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product, including Plaintiff herein, without substantial change in the condition in which the Device was designed, produced, manufactured, sold, distributed, and marketed by Defendants.

62. The Device's unsafe, defective, and inherently dangerous condition was a cause of injury to Plaintiff herein.

63. The Device failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

64. The injuries to Plaintiff herein resulted from use of the Device in a manner that was both intended and reasonably foreseeable by Defendants.

65. At all times herein mentioned, the Device posed a risk of dangers inherent in the design which outweighed the benefits of such design of the Device for patients including Plaintiff herein.

66. At all times herein mentioned, the Device was defective and unsafe, and Defendants knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by Defendants.

67. At all times herein mentioned, Defendants knew, or should have known, that the Device was in a defective condition, and was and is inherently dangerous and unsafe to patients such as Plaintiff herein.

68. At the time of the implantation of the Device into Plaintiff herein, the aforesaid Device was being used for the purposes and in a manner normally intended, namely for use as a hip replacement device.

69. Defendants, with this knowledge, voluntarily designed their Device in a dangerous condition for use by the public, including Plaintiff herein.

70. Defendants had a duty to Plaintiff and other patients to create a product that was not unreasonably dangerous for its normal and intended use.

71. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, including Plaintiff herein, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff as a result of implantation of the defective Device.

72. As a direct and proximate result of Defendants' placement of the defective Device into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

73. Further, as a result of the foregoing acts and omissions, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $75,000.00, together with the costs of this action, post-judgment interest, and such other relief as this Court deems just. Plaintiff further demands trial by jury.

COUNT II
STRICT LIABILITY FOR INADEQUATE WARNING

74. Plaintiff incorporates by reference, as if fully set forth herein, paragraphs 1 through 73 above, as to all Defendants and further alleges as follows.

75. At all times herein mentioned, Defendants designed, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed into the stream of commerce the Device that was surgically implanted in Plaintiff herein.

76. The Device was defective due to inadequate warnings, as Defendants knew or should have known that the Device could fail early in patients, including Plaintiff herein, and therefore give rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the Device with the attendant risks of complications and death from such further surgery, but failed to give consumers, such as Plaintiff, adequate warning of such risks.

77. The Device is unsafe and inherently dangerous due to inadequate warnings because it was sold to Plaintiff without adequate warnings regarding the following unsafe conditions, propensities, and risks of the Device: to loosen and cause serious pain and necessitate additional surgery; to generate metal debris resulting in metallosis and increased cobalt and chromium levels; to cause damage to soft tissue and bone; to subject the patient to possible cancer and other potential harm due to elevated metal ions and metallosis.

78. The Device was defective, unsafe, and inherently dangerous due to inadequate warnings at the time that it left Defendants' possession and was placed into the stream of commerce.

79. At all times herein mentioned, the Device and its associated instructions and warnings were expected to and did reach the usual consumers, handlers, and persons coming into contact with said product, including Plaintiff herein, without substantial change in the condition in which the Device and its associated instructions and warnings were designed, produced, manufactured, sold, distributed, and marketed by Defendants.

80. The Device's unsafe, defective, and inherently dangerous condition due to inadequate warnings and instructions were the cause of injury to Plaintiff herein, and those injuries were reasonably foreseeable by Defendants.

81. As a direct and proximate result of Defendants' placement of the Device with its inadequate and defective warnings and instructions for use into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

82. Further, as a result of the foregoing defects in the instructions and warnings that accompanied the Device, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $75,000.00, together with the costs of this action, post-judgment interest, and such other relief as this Court deems just. Plaintiff further demands trial by jury.

COUNT III
STRICT LIABILITY FOR MANUFACTURING DEFECT

83. Plaintiff incorporates by reference, as if fully set forth herein, paragraphs 1 through 82 above, as to all Defendants and further alleges as follows.

84. At all times herein mentioned, Defendants designed, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed into the stream of commerce the Device that was surgically implanted in Plaintiff herein.

85. The Device that was surgically implanted in Plaintiff was defective in its manufacture when it left the hands of Defendants in that the Device deviated from product specifications and/or performance standards of the manufacturer and posed a serious risk that the Device could fail early in patients, such as occurred when the Device was implanted in Plaintiff herein, therefore giving rise to physical injury, pain and suffering, debilitation, and the need for a revision surgery to replace the Device with the attendant risks of complications and death from such further surgery.

86. As a direct and proximate result of Defendants' placement of the defective Device into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

87. Further, as a result of the foregoing acts and omissions and manufacturing defects in the Device, Plaintiff has suffered and/or will in the future suffer lost wages and diminished capacity to earn wages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $75,000.00, together with the costs of this action, post-judgment interest, and such other relief as this Court deems just. Plaintiff further demands trial by jury.

COUNT IV
BREACH OF EXPRESS WARRANTY

88. Plaintiff incorporates by reference, as if fully set forth herein, paragraphs 1 through 87 above, as to all Defendants and further alleges as follows.

89. At all times herein mentioned, Defendants designed, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed into the stream of commerce the Device that was surgically implanted in Plaintiff herein.

90. Defendants expressly warranted the following: that the Device was a safe and effective hip replacement implant; that the Device would last longer than a traditional polyethylene-lined implant, and that the longer lifespan of the Device made it more appropriate for implantation in young and active patients, such as Plaintiff herein.

91. Indeed, as set forth in detail above, Defendants made numerous representations about the quality, safety, effectiveness, and expected lifespan of the Device which form express warranties to consumers, including Plaintiff herein.

92. The Device, when placed into the stream of commerce by Defendants, did not conform to these express representations because the Device failed prematurely, thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for a revision

surgery to replace the Device with the attendant risks of complications and death from such further surgery.

93. As a direct and proximate result of Defendants' breach of express warranties regarding the safety and effectiveness of the Device, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

94. Further, as a result of the foregoing acts and omissions and breach of express warranties regarding the safety and effectiveness of the Device, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $75,000.00, together with the costs of this action, post-judgment interest, and such other relief as this Court deems just. Plaintiff further demands trial by jury.

COUNT V
NEGLIGENCE

95. Plaintiff incorporates by reference, as if fully set forth herein, paragraphs 1 through 94 above, as to all Defendants and further alleges as follows.

96. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, selling, testing, assuring quality, and/or distributing the Device into the stream of commerce, including a duty to assure that the Device would not cause patients in whom the Device was surgically implanted, such as Plaintiff herein, to suffer harmful effects and injuries caused by the Device.

97. Defendants failed to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, selling, testing, assuring quality, and/or distributing the Device into the stream of commerce in that Defendants knew or should have known that patients who were surgically implanted with the Device, including Plaintiff herein, were at risk for suffering harmful effects and injuries caused by the Device including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

98. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Negligently designing the Device in a manner which was dangerous to those individuals who had the Device surgically implanted, including Plaintiff herein;

b. Designing, manufacturing, producing, creating, and/or promoting the Device without adequately, sufficiently, or thoroughly testing it;

c. Failing to conduct sufficient testing programs to determine whether or not the aforesaid Device was safe for use in patients such as Plaintiff herein;

d. Failing to inform patients, including Plaintiff herein, and surgeons, including Plaintiff's original implanting surgeon, that the Device was unsafe and unfit for use due to its defective condition, inherently dangerous, dangerous beyond the extent that would be contemplated by an ordinary consumer with ordinary knowledge as to the Device's characteristics, and the fact that the risks of use of the Device outweighed the Device's benefits;

e. Selling the Device without making proper and sufficient tests to determine the dangers that the Device posed to patients, including Plaintiff herein;

f. Negligently failing to adequately and correctly warn Plaintiff or Plaintiff's physicians, hospitals and/or healthcare providers of the dangers of the Device;

g. Negligently failing to recall their dangerous and defective Device at the earliest date that it became known that the Device was, in fact, dangerous and defective;

h. Failing to provide adequate instructions regarding safety precautions to be observed by surgeons who would reasonably and foreseeably come into contact with, and more particularly, implant the Device into their patients;

i. Negligently advertising and recommending the use of the Device despite the fact that Defendants knew or should have known of its dangerous propensities;

j. Negligently representing that the Device offered was safe for use for its intended purpose, when, in fact, it was unsafe;

k. Negligently manufacturing the Device in a manner which was dangerous to those individuals who had it implanted, including Plaintiff herein;

l. Negligently producing the Device in a manner which was dangerous to those individuals who had it implanted, including Plaintiff herein;

m. Negligently assembling the Device in a manner which was dangerous to those individuals who had it implanted, including Plaintiff herein;

n. Under-reporting, under-estimating, and downplaying the serious dangers associated with use of the Device;

o. Negligently designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and/or sale of the

Device in that they failed to use due care in designing and manufacturing the Device so as to avoid the aforementioned risks to patients who had the Devices surgically implanted, including Plaintiff herein;

p. Negligently designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and/or sale of the Device in that they failed to accompany the Device with proper warnings and instructions for use;

q. Negligently designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and/or sale of the Device in that they failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Device;

r. Acting with willful, reckless and wanton misconduct in allowing the dangerous and defective Device to be implanted in patients, including Plaintiff herein, without sufficient testing and with express knowledge of enhanced risks, and

s. Otherwise acting with careless and/or negligent disregard for the health and safety of patients, including Plaintiff herein.

99. Despite the fact that Defendants knew or should have known that the Device caused harm to patients in whom the Device was surgically implanted, including Plaintiff herein, Defendants continued to market, manufacture, distribute, and/or sell the defective and unreasonably dangerous Device.

100. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injury and/or be at risk of suffering injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

101. Defendants' negligence was the proximate cause of Plaintiff's physical, mental, and emotional injuries and harm, and economic losses which Plaintiff has suffered and/or will continue to suffer.

102. As a direct and proximate result of Defendants' failure to exercise ordinary care and negligent acts as outlined above with regard to placement of the defective Device into the stream of commerce, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

103. Further, as a result of the foregoing failure to exercise ordinary care and negligent acts of Defendants, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount in excess of $75,000.00, together with the costs of this action, post-judgment interest, and such other relief as this Court deems just. Plaintiff further demands trial by jury.

COUNT VI
NEGLIGENT MISREPRESENTATION

104. Plaintiff incorporates by reference, as if fully set forth herein, paragraphs 1 through 103 above, as to all Defendants and further alleges as follows.

105. Defendants supplied false information to the patients, including Plaintiff herein, and to surgeons, including Plaintiff's surgeons, regarding the claimed superior quality, safety, and effectiveness of the Device. Defendants provided this false information to induce patients,

including Plaintiff herein, and surgeons, including Plaintiff's original implanting surgeon, to purchase and implant the Device.

106. Defendants knew or should have known that the information that Defendants supplied regarding the purported superior quality, safety, and effectiveness of the Device would induce Plaintiff and Plaintiff's physicians to purchase and use the Device and that such information was false and misleading.

107. Defendants were negligent in obtaining or communicating false information regarding the purported superior quality, safety, and effectiveness of the Device.

108. Plaintiff and Plaintiff's physicians relied on the false information supplied by Defendants to Plaintiff's detriment in that such false information led to the purchase of the Device and implantation of the Device into Plaintiff's body, which have subsequently caused severe injury and catastrophic damages to Plaintiff.

109. Plaintiff and Plaintiff's physicians were justified in their reliance on the false information supplied by Defendants regarding the purported superior quality, safety, and effectiveness of the Device.

110. As a direct and proximate result of Defendants' negligent misrepresentations, Plaintiff experienced and/or will experience severe harmful effects, which are permanent and lasting in nature, including, but not limited to, the following: partial or complete loss of mobility; loss of range of motion; physical pain and suffering; mental anguish; diminished enjoyment of life; need for revision surgery; increased risk of complications due to revision surgery and metallosis; and potential for systemic disease and cancers associated with elevated metal ions and metallosis.

111. Further, as a result of the foregoing negligent misrepresentations, Plaintiff has suffered and/or will in the future suffer lost wages and a diminished capacity to earn wages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

2. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages in an amount to be determined at trial of this action;

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

4. Prejudgment interest;

5. Post-judgment interest;

6. Awarding Plaintiff reasonable attorneys' fees;

7. Awarding Plaintiff the costs of these proceedings; and

8. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.

Dated: January 24, 2017.

Respectfully submitted,

Nancy A. Mismash, 6615
Robert J DeBry & Associates
4252 South 700 East
Salt Lake City, UT 84107
(801) 262-8915
Email: nmismash@robertdebry.com